REMARKS

Claims 1-11 are pending in this application.

Applicants note that this Response is being filed concurrently with and as part of a Petition to Revive the present application.

Obviousness Rejections

Claims 1-11 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over the combination of the Nordette monograph and the Alesse monograph in view of Katzung and Endrikat *et al.* The rejection is repeated nearly verbatim from an earlier office action.

Applicants respectfully assert that the office has not established a *prima facie* case of obviousness. The art does not teach or suggest a kit including at least two oral contraceptive cycle packs, where the last cycle pack contains oral contraceptives having a steroid content lower than that of the penultimate cycle pack, with or without instructions. There simply is no showing of a motivation to combine the references to achieve the claimed kit.

The Action states "it would have been obvious to one skill[ed] in the art when the invention was made to incorporate both Nordette and Alesse together with a written description of how to take the oral con[tra]ceptive into a kit for oral contraception." According to the Action, combining two compositions which are known to be useful for oral contraception individually into a single pharmaceutical kit useful for the very same purpose is *prima facie* obvious, absent evidence to the contrary, citing *In re Kerkhoven*, 205 USPQ 1069.

Applicants respectfully assert that *Kerkhoven* suggests that the combination of two products, useful for the same purpose, into a single composition for that same purpose is obvious. It does not stand for the proposition that when two original products are left as individual products, but packaged as a kit for physically and temporally separate administration, that the kit is obvious in light of the original individual products, as suggested by the Action. *Kerkhoven* merely requires a showing of unexpected results when two products achieving a certain result are combined into a single composition to achieve the same result. This is not the case here.

Here, Applicants have recognized that two products, such as Nordette and Alesse, are each effective contraceptives but when administered under a certain regime provides benefits not seen by administration of either product alone. Nordette contains 30 μg EE while Alesse contains 20μg EE. Under the Actions' proposal, it would be obvious to provide a kit having at least one cycle pack of Nordette with one cycle pack of Alesse, since both are contraceptives. Such a combination, however is not taught or suggested in the art. Indeed, the art does not suggest multi-cycle contraceptive kits, and certainly does not disclose inclusion of multi-cycle kits of differing EE content.

Katzung is cited as showing the use of different steroids in different combinations. Importantly, Katzung also shows the well-known technique of placing contraceptives of different content levels within a single cycle pack for use in a single cycle and repeated in subsequent cycles. Katzung, however, does not teach or suggest altering the content (or even the sequence

of contents) from one cycle to the next. This is in sharp contrast to Applicants' claimed kit, where the steroid content varies from the penultimate cycle pack to the last cycle pack.

Endikrat *et al.* is cited because it shows that contraceptives containing 30 μg of the steroid ethinyl estradiol (hereafter EE) demonstrate reduced levels of breakthrough bleeding or spotting compared to a similar contraceptive containing just 20 μg EE, particularly in the first 3 months. The reference teaches the mutually exclusive administration of one contraceptive, either the 30 μg EE or the 20 μg EE, to each patient in the study over the entire course of treatment. The course of treatment lasted for twelve cycles. No patient switched from the 30 μg EE contraceptive to the 20 μg EE contraceptive at any time during the evaluation period. The reference is utterly silent with respect to switching from one contraceptive to another and recognizes only that the 30μg EE contraceptive has less bleedthrough and spotting particularly in the initial transition period.

Applicants, for the first time, recognized that significant benefits, in the form of reduced bleedthrough and spotting in the first few months, can be achieved by using initial cycles of relatively high levels of steroid while in subsequent months the reduced bleedthrough and spotting could be maintained by lower steroid doses. Subsequent lower doses reduce the risks recently thought to be associated with higher steroid doses. Prior to applicants discovery, conventional wisdom was to find an oral contraceptive that was well-tolerated, and to continue taking the same contraceptive over an entire treatment period without altering administration regimes from one cycle to the next. The Nordette monograph, itself, suggests this practice, by

indicating that continued problems with spotting and bleedthrough can be overcome by switching formulations or simply through the passage of time.

Applicants respectfully assert that the Office has not established a *prima facie* case of obviousness, because the Action does not provide any factual evidence of the motivation to combine or modify the teachings of the references. The CAFC has repeatedly admonished the Office of the dangers of hindsight reconstruction. In *Ecolochem, Inc. v. So. Cal. Edison, Co.*, 227 F.3d 1361; 56 USPQ2d 1065 (Fed. Cir. 2000) (Rehearing denied at 2000 U.S. App. LEXIS 34050; Cert denied at 2001 U.S. LEXIS 2957) the CAFC stated "[o]ur case law makes clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." (Internal citations and quotations omitted.)

Here, as in the District Court's opinion in *Ecolochem*, the rejection "does not discuss any specific evidence of motivation to combine, but only makes conclusory statements. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *Ecolochem* at 1372. In fact, the only rationale provided for combining the references is the inapplicable rationale of *Kerkhoven*, discussed above. The rejection does not point to any specific teaching or suggestion in any of the references or any factual evidence that would have led one skilled in the art, at the time of filing, to package at least two oral contraceptive cycle packs with differing steroid concentration, as presently claimed.

In the present case, only Applicants' specification teaches the benefits and motivation for altering dosing regimes from one cycle to the next. Heretofore, the conventional wisdom was to maintain dosing regimes from one cycle to the next, although within each cycle, one or more compositions or doses could be employed. Even where intra cycle compositions or doses varied from dose to dose, those regimes were repeated in the next cycle.

At best the art suggests that where bleedthrough and spotting are a continual problem, a different oral contraceptive formulation should be tried. Indeed, the recommendation for a different formulation is not necessarily directed to different steroid content, but is an indication to try a different oral contraceptive altogether. This is a far cry from Applicant's discovery that a planned approach of altering steroid content after an initial introductory period reaps the benefits of reduced bleedthrough/spotting in the initial transition period and the benefits of a safer maintenance dose after the transition period.

The Office simply has not shown any evidence of a motivation to alter steroid doses from cycle to the next. Absent such motivation, there can be no motivation to provide a kit containing multiple cycle packs having oral contraceptive content to facilitate a dosing regime employing such altered doses. Accordingly, the Office has not met the burden of showing a *prima facie* case of obviousness.

Early reconsideration and allowance of all pending claims is respectfully requested. The examiner is requested to contact the undersigned attorney if an interview, telephonic or personal, would facilitate allowance of the claims.

The Commissioner is hereby authorized to charge any required fee to Deposit Account No. 50-1275 for this Response or the associated Petition For Revival. This authorization can also be found on the Fee Transmittal filed herewith.

Respectfully submitted,

COZEN O'CONNOR

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By: Michael A. Patané
Reg. No. 42, 982

1900 Market Street, 5th Floor
Philadelphia, PA 19103-3508
215-665-6966 – Telephone No.
215-701-2080 – Facsimile No.

Phila1\2099170\1